Maryland Board of Pharmacy Public Meeting Minutes

Date: August 18, 2010

Name	Title	Present	Absent	Present	Absent
Anderson, C.	Commissioner	Х		2	0
Bradley-Baker, L.	Commissioner		Х	1	1
Chason, D.	Commissioner	Χ		1	1
Finke, H.	Commissioner	Х		2	0
Handelman, M.	Commissioner	Χ		2	0
Israbian-Jamgochian, L.	Commissioner/Treasurer	Х		2	0
Matens, R.	Commissioner	Χ		2	0
Souranis, M.	Commissioner//President	Х		2	0
St. Cyr, II, Z. W.	Commissioner	Х		1	
Taylor, D.	Commissioner	Χ		2	0
Taylor, R.	Commissioner/Secretary	Х		2	0
Zimmer, R.	Commissioner	Х		1	1
Bethman, L.	Board Counsel	Х		2	0
Gibbs, F.	Board Counsel	Х		2	0
Banks, T.	MIS Manager		Х	1	1
France, K.	Compliance Manager	Х		2	0
Gaither, P.	Administration and Public Support Manager	Х		2	0
VACANT	Licensing Manager			0	0
Jeffers, A.	Legislation/Regulations Manager	Х		2	0
Naesea, L.	Executive Director	Х		2	0
Waddell, L.	Executive Secretary	Х		2	0
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Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
I. Executive Committee Report(s)	A. M. Souranis, Board President	Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.		
		 R Taylor called the Public Meeting to order at 9:05 a.m. R. Taylor requested all meeting attendees to introduce themselves and to remember to sign the guest list before leaving the meeting. M. Souranis asked guest to (Please indicate on sign-in sheet if you are requesting CE Units for attendance). R. Taylor reported that guest will be given packets of materials so that they can follow meeting discussions. He requested that all guest return their draft packets before they leave the meeting R. Taylor asked all members of the Board with a conflict of interest relating to any item on the agenda to notify the Board at this time or when the issue is addressed in the agenda. Review & Approval of Minutes of July 21, 2010 Page 8, Section III A, Discussion Item. Item A remove "contest" and add "context". Page 12, Section III A, Motion Item. Item 4b remove "C. Anderson made a motion and add "C. Anderson was recused. 	5. Motion: R. Zimmer made a motion to approve the July minutes as amended.	5. Board Action: The Board voted to approve the minutes.

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	. a.r.y		R. Matens seconded the motion.	
II. Staff Operations Report (s)	A. L. Naesea, Executive Director	1. L. Naesea reported on the following Operation Updates: a. The Licensing Manager position is vacant. L. Naesea splits her time between the Licensing Unit and her duties as the Executive Director. b. K. France and the Compliance Unit pulled together all disciplinary actions to be posted on the website. c. The Licensing Unit completed the backlog of completed applications. L. Naesea reported that there are too many applications for review during the Licensing Committee meeting and the Committee may need to meet more than once a month. d. The Board has not recruited a manager for the Licensing Unit at this time. The Licensing Unit processes need to be reorganize before someone is appointed for the position. The salary of the position is a grade 14 which may be too low to attract someone with experience. The Board would like to recruit someone from another Licensing Board that has experience but the grade may be too low for the volume of work and level of responsibility. e. The Legislative Auditors are meeting with all Board Directors on Tuesday, August 24, 2010 to brief the Boards on the Legislative Audit process.		
	B. P. Gaither, APS Manager	a. The Board is waiting on a freeze exempt for the Licensing Manager position. b. N. Richards was re-classed to the Lead Inspectors position. A desk audit was done on the position and the auditors down graded the position. L. Nausea will appeal the decision of the auditors. c. The Board received the freeze exemption for the Licensing Secretary position and the recruiting process will end on August 23,		

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		2010.	, ,	
		d. The Board has received a letter of resignation from Colin Eversely,		
		Compliance Investigator. Effective August 31, 2010. He will be		
		moving to Atlanta, GA.		
		e. Law books were ordered 4,000 law books, 500 CD's waiting for		
		purchase order.		
		f. The automation contract is on short-term bid.		
		g. The summer newsletter is completed. Fall articles are due on		
		September 10, 2010 to Janet Seeds.		
		h. The annual report articles deadline in September 15, 2010.		
		i. The Budget for 2011 has closed out. The 2012 budget has been		
		approved and submitted and the Board is expecting the purchase of 2 additional vehicles.		
		j. The Public Relations committee recommended that Janet mail		
		newsletters to permit holders only and post on the website.		
		Don recommends that the project is postponed until the Board can		
		acquire e-mail addresses for all pharmacies and pharmacists.		
		k. The CE Breakfast will be held on October 3, 2010 at the Radisson		
		at Cross Keys. The Board is preparing to send out invitations to		
		Pharmacist who has practiced Pharmacy for 60 years.		

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	C. T. Banks, MIS Manager	1. L. Naesea reported that MIS has revised some of the database systems to meet the recommendations of the internal auditors.		
	D. K. France, Compliance Unit Manager	K. France reported on the statistics for PEAC.		
	E. A. Jeffers, Rgs/Lgs. Manager	A. Jeffers reported on the following Status of Proposed Regulations:		
		a <u>10.34.25 Delivery of Prescriptions</u> Submitted August 4, 2010 for publication.		
		b. 10.34.35 Home Infusion Pharmacy Services To be submitted to the Practice Committee in August.		
		c. 10.13.01 Dispensing of Prescription Drugs by a Licensee The Board has invited representatives from the stakeholder Boards to join us for a meeting per direction from Wendy Kronmiller and waiting for a response.		
		A. Jeffers reported on the following Status of Proposed Legislation:		
		a. Legislative Proposal submitted to the Office of Governmental Affairs on July 14, 2010: Health Occupations - Pharmacy – Licensure of Pharmacists		
		b. Legislative "place holder" submitted to the Office of Governmental Affairs on July 14, 2010: Health-General – Prescription Drug Repository Program – Disposal		
		3. Medical Orders for Life Sustaining Treatment Comments Solicited	3. C. Anderson made a motion to	3. Board Action: The Board voted
		MOLST Draft Documents 073010 The Board approved responding to Dr. Nay that the Board held its	respond to the letter.	to approve the motion.

Field Code Changed	
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		monthly Public Board Meeting and discussed whether it would be preferable for the individual order choices on the MOLST form to be indicated by an "x" or check mark in a box, or by having each selected option initialed. The Board's preference is each selected option should be initialed.	D. Chason seconded the motion.	
III. Committee Reports	A. R. Zimmer, Chair, Practice Committee	1. Review of Draft Regulations a. 10.34.03 Inpatient Institutional Pharmacy (i) Board responses to informal comments to be approved today. Draft proposal - 10.34.03 - released for Informal 062410 Informal Comments and Board Responses: 1. Jacob Raitt - Informal Comment - 10.34.03 Board Response to Informal Comment - 10.34.03 - Jacob Raitt 2. JHMI - Informal Comment - 10.34.03 071610 Board Response to Informal Comment - 10.34.03 - JHMI 3. KWalter - Sheppard - Informal Comment - 10.34.03 - Sheppard 4. Md Hosp Assoc - Valarie Shearer Overton - Informal Comment - 10.34.03 rtf Board Response to Informal Comment - 10.34.03 - Md Hosp Assoc. 5. Thomas - Informal Comment - Institutional practices - submi_1 Board Response to Informal Comment - 10.34.03 - Thomas Discussion ensued concerning the Board's response to Jennifer Thomas and Kristen Webb at JHMI. The concerns included: order sets, frequency of review of policies and procedures, initials on master logs, and appropriateness of obtaining height, pregnancy status and lactation status information. (ii) Revised proposal to be approved for submission for publication.	1. a. Motion C. Anderson made a motion to table Board responses 1 through 5 and send the responses and the proposal back to Practice Committee for review. D. Taylor seconded the motion.	1. a. Board Action The Board voted to approve the motion.

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	-	Draft proposal - 10.34.03 - released Informal 062410 rev 072810 & by Don		
		Returned to Practice for revisions pursuant to the Board's revised responses to comments.		
		b. 10.34.20 Format of Prescription Transmission (i) Board responses to official comments to be approved today.		
		<u>Kaiser Permanente - Formal comments 10.34.20 7.5.10</u> Board Response to Comment – 10.34.20 – Kaiser Permanente	b (i) 1. Motion: R. Matens made a motion to approve the letter.	1. b. (i)1. Board Action: The Board voted
		2. NACDS - Diane Darvey - Formal Comment - 10 34 20 July 2010 Board Response to Comment - 10.34.20 - NACDS	R. Zimmer seconded the motion.	to approve the motion.
		3. VetCentric, Inc Formal Comments 10.34.20 Board Response to Comment – 10.34.20 – VetCentric, Inc.	1. b. (i) 2. Motion: D. Taylor made a motion to approve the letter as	1. b. (i) 2. Board Action: The Board voted to approve the
		Below is a summary of the Board's revised responses:	amended.	motion.
		It was requested that a pharmacy student under the supervision of a pharmacist be able to take an original oral prescription by a voice messaging system or by phone with the pharmacist using his or her professional judgment to determine if reading back of the prescription is necessary.	H. Finke seconded the motion.	
		A pharmacy student in an experiential learning program may take an original oral prescription directly from a prescriber or by a voice messaging system at the discretion of the supervising pharmacist.	1. b. (i) 3. Motion: D. Taylor made a motion to approve the letter as amended.	1. b (i) 3. Board Action: The Board voted to approve the motion.
		Reading back an oral prescription to a prescriber applies to when the pharmacist is actually talking to the prescriber. If the prescriber does not cooperate, then the pharmacist may make a note of it in the prescription record. It is assumed if the pharmacist does not understand a prescription on a voice messaging system, that the pharmacist will play the message back or contact the prescriber for clarification.	D. Chason seconded the motion.	

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		.02A(2)(b)(i) – (iii) It was questioned whether the requirements of .02A(2)(b)(i) – (iii) stood alone or whether (i) through (iii) all had to be satisfied for an electronic prescription to be valid. The regulation states:		
		A valid prescription shall be conveyed in a manner that is transmitted to the pharmacy electronically, provided that the prescription is:		
		(i) Transmitted via electronic intermediaries that are certified by the Maryland Health Care Commission;		
		(ii) Received by the permit holder's computer, facsimile machine, or other electronic device; and		
		(iii) Maintained by the permit holder in accordance with Regulation .03 of this chapter; or		
		(c) In an oral manner where:		
		(i) Only a pharmacist may take an original oral prescription by a voice messaging system or by phone with the pharmacist reading back the prescription to the prescriber or the prescriber's agent; and		
		(ii) The pharmacist promptly reduces the oral prescription to writing.		
		It is the intent of the Board, and the above section clearly indicates by use of the word "and" after .02A(2)(b)(ii), that all three conditions must be met for an electronic prescription to be valid.		
		The Board would like to thank you again for your thorough reading of the		
		proposed COMAR 10.34.20 Format of Prescription Transmission. The Board		
		considered all comments received at the August 18, 2010 Board Meeting and		
		voted to adopt COMAR 10.34.20 as proposed.		
		(ii) Approve adopting proposal as published. Anticipated Effective date would be September 20, 2010.	1. b. (ii). Motion: D. Chason made a	1. b. (ii). Board Action:

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		Md. R. June 4, 2010 COMAR 10.34.20	motion to adopt the proposal as published.	The Board voted to approve the motion.
		The Board approved adopting as published.	R. Matens seconded the motion.	
		c. 10.34.23 Pharmaceutical Services to Patients in Comprehensive Care		
		Facilities Notice of Final Action ready for submission for publication with the effective date of _10/18/2010.	C. Motion: D. Taylor made a motion to accept the final date of publication.	1. c. Board Action: The Board voted to approve the motion.
		The Board approved adopting as proposed with the effective date of October 18, 2010.	M. Handelman seconded the motion.	
		d. 10.34.28 Automated Medication Systems Submitted for publication on August 5, 2010. Board response to Kaiser Permanante to be approved today. COMAR Comment - 10.34.28 Kaiser Permanente – Friedman Board Response – Kaiser - Friedman Board Response – Comment from July Bd Mtg – 10.34.28 – KP	1. d. Motion: D. Taylor made a motion to provide language to accommodate "selecting" of medications by pharmacy technicians from bulk drugs.	1. d. Board Action: The Board voted to approve the motion.
		The Board's response to Kaiser Permanente's comment and the proposal will be revised to accommodate pharmacy technicians "selecting" of medications from bulk drugs.	D. Chason seconded the motion.	
		e. CLIA – On Hold until LAC meets August 31, 2010. Fwd Scanned from Lexmark Model X658 image2010-08-03-090618	1.e. Action Item: R. Zimmer will attend the meeting to represent the Board	
		Reid Zimmer will attend the LAC meeting on August 31, 2010 on behalf		

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		of the Board. f. Pharmacist review in Assisted Living Facilities	1. f. Motion: L. Israbian-	1.f. Board Action:
		<u>Draft Letter to OHCQ requesting revision to 10.07.14.29 requiring</u> quarterly pharmacist review.	Jamgochian made a motion to accept the letter as revised.	The Board voted to approve the motion.
		Delaware Regulations	M. Handelman seconded the motion.	
		The Board's letter to OHCQ as revised: As you know, on December 29, 2008, COMAR 10.07.14 Assisted Living Programs became effective. Within this chapter, Regulation .29 Medication Management and Administration requires a pharmacist to conduct on-site reviews in assisted living facilities of physicians prescriptions, physician orders, and resident records at least every 6 months for any resident receiving nine or more medications, including over the counter and PRN (as needed) medications. At the time the Board of Pharmacy had recommended a more frequent review of quarterly, but the assisted living community and the Office of Health Care Quality would only agree to every 6 months.		
		It has come to the attention of the Board of Pharmacy that the neighboring State of Delaware's Division of LTC Residents Protection requires pharmacist review of assisted living facilities on a quarterly basis. The Maryland Board of Pharmacy would like to request that the Office of Health Care Quality revisit COMAR 10.17.14.29 to consider proposing a revision to the regulation requiring pharmacists to conduct on-site reviews of assisted living facilities of physicians prescriptions, physician orders, and resident records at least every 3 months for any resident receiving nine or more medications, including over the counter and PRN (as needed) medications.		
		This revision would further protect the health of residents in assisted living facilities by preventing the use of unnecessary medications and preventing dangerous medication interactions. 2. Review of Draft Legislation - None		

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Subject		3. A. Jeffers reported on the following Draft Response Letters: a) Lester Zuckerman, physician dispensing LTC - nursing home physicians dispensing 061810 nursinghome physicians Email to Practice - nursinghome physicians - Lester Zuckerman (with Reid's revision) The letter was approved with revisions and Reid Zimmer worked with Anna Jeffers before it was sent. The letter reads: 1) Is it possible to transfer one needed medication from one location		Board Action 3. a. Board Action: The Board voted to approve the motion.
		or facility to another SNF? If the answer is yes, can it be sent to the other facility in the SKY Unit Dose Packaging provided that the lot numbers and manufacturer expiration dates are on the labels of dispensed prescriptions? No, it is not possible to transfer one needed medication from one location or facility to another SNF. Medications dispensed pursuant to a patient specific order must be dispensed by a pharmacy, or an authorized prescriber with a dispensing permit, to that specific patient only. Additionally, an authorized prescriber with a dispensing permit is required to comply with COMAR 10.13.01.04 Dispensing Requirements.		
		2) Also, can this group obtain other impromptu prescription drugs from another long-term care pharmacy or local pharmacy? Physicians may purchase prescription drugs for office use, or for dispensing to their patients, from a full service pharmacy or a waiver pharmacy pursuant to an invoice. See Health Occupations Article, 12-102, Annotated Code of Maryland. Some waiver pharmacies (long term care pharmacies) may have restricted their permits to only dispense to long term care patients and their permits may not permit them to sell to authorized prescribers pursuant to an invoice.		

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		b)_Alyssa Albinak,Pharmacist Transfers of Rx between a retail pharmacy & a waiver pharmacy servicing institutions Draft – transfers – LTC to retail	3 b. Motion: Practice Committee made a motion to approve the letter as written.	3 b. Board Action: The Board voted to approve the motion.
		Thank you for contacting the Maryland Board of Pharmacy concerning whether a retail pharmacy may transfer a prescription from a closed door pharmacy servicing institutional facilities.	D. Chason seconded the motion.	
		If you are referring to an order from a pharmacy that services a long term care facility there may not be enough information to qualify the order as a prescription. You would be obligated to contact the prescriber for verification of the information.	3c. Motion:	
		c) Marc Summerfield, UMM Unlicensed personnel – Marc Summerfield Draft – Unlicensed personel – chckg expiration dates	Practice Committee made a motion to approve the letter as written.	3c. Board Action: The Board voted to approve the motion.
		Unlicensed personnel may perform operational support tasks. Since one of the operational support tasks is to perform stocking, then the inventory control clerk may check expiration dates of medications. See the Code of Maryland Regulations (COMAR) 10.34.21.02	D. Chason seconded the motion.	
		d) Ms. Holder Re Delivery service - RX medication delivery to patients home Draft - Deliver Service	3d. Motion: Practice Committee made a motion to approve the letter as written.	3d. Board Action: The Board voted to approve the motion.
		The Maryland Pharmacy Act does not address a small business delivery service that picks up patient's prescriptions, takes them to the pharmacy and delivers medications from the pharmacy to the patient's residence. Please check with the Centers for Medicare and Medicaid Services for their requirements. www.cms.gov	C. Anderson seconded the motion.	R. Matens opposed

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		4. A. Jeffers reported on the following Letters for Board Approval		4. a. Board Action:
		a) Patrick de Gravelles, CareFirst Care First - Patrick de Gravelles – home infusion	4a. Motion: C. Anderson made a motion to approve the letter	The Board voted to approve the motion.
		Draft - Home Infusion - Full Service Pharmacy Permit	as written.	
		Assuming that the pharmacy or its personnel entered patients' homes to provide support as outlined above, was the pharmacy acting in accordance with its full service license prior to receiving an RSA; and	H. Finke seconded the motion.	
		Yes, the pharmacy was acting in accordance with its full service license under the Maryland Pharmacy Act. A full service pharmacy may provide medications if it is pursuant to a valid patient specific prescription.		
		2) Assuming that the pharmacy only shipped the factor products and supplies to patients' homes via common carrier, and there was no other healthcare provider who had an RSA overseeing the home-based therapy, was the pharmacy acting in accordance with its full service license prior to receiving an RSA?		
		Dispensing a prescription pursuant to a patient specific prescription is in compliance with the Maryland Pharmacy Act. The pharmacy is not obligated to train the patient.		
		b) Michael Scozzaro, Wegmans	4b. Motion: C. Anderson made	4b. Board Action:
		Wegmans - MJ Scozzaro - Pharm Tech	a motion to approve the letter as written.	The Board voted
		Draft - Pharm Tech - informing patient of color, size, shape of tablet		to approve the motion.
		A registered pharmacy technician may inform a patient that their medication may look different, so long as that is the only information provided. Any questions would be required to be referred to the pharmacist.	D. Chason seconded the motion.	
		c) Amy Larson, Target	4.c. Motion: R. Matens made a	4.c. Board Action:

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		Target - Amy Larson - Pharmacy Staffing Draft - Closing - minor events Please be advised that for minor emergency closures, the permit holder does not need to notify the Board.	motion to approve the letter as amended. C. Anderson seconded the motion.	The Board voted to approve the motion.
		d) Laura Carpenter, Carpenter Law Firm Consolidation of refills to allow patients to obtain 90-day supplies covered on their insurance Draft – refills – providing 90 day supply	4.d. Motion: D. Chason made a motion to approve the letter as amended.	4.d. Board Action: The Board voted to approve the motion.
		The Board does not regulate payment issues, however; please be advised that providing refills at the first fill may be dictated by insurance and third party payors. The pharmacist should contact the prescriber to have the prescription changed so that the total amount of the refills may be dispensed at once.	C. Anderson seconded the motion.	motion.
		e) Al Carter, Walgreens Walgreens - elec records – stickerless	4e. Motion: C. Anderson made a motion to approve the letter as amended.	4e. Board Action: The Board voted to approve the motion.
		Draft – records – elec – stickerless The Board does not prohibit scanning prescriptions, however; please be advised that the Board has concerns about the clarity of scanning and the potential for errors for the pharmacist with only the scanned copy available for final verification. It was noted in the materials Walgreen's is providing to its Maryland stores that any "non-scannable" prescription will be re-written by hand and then scanned.	D. Chason seconded the motion.	
		This would result in the scan of a prescription that is not the original prescription relying on another's interpretation. As you know, you may not rewrite a Schedule II controlled dangerous substance.		

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		Workgroup/Sub-committee/Task Force Reports a. Legislative Committee – report on meeting with Delegate Butterly		
		Rudolph. Anna Jeffers reported on the meeting with Delegate Rudolph where Mike Souranis, Lenna Israbian-Jamgochian, and Dave Chason also attended. There was a brief discussion on physician dispensing. There was further discussion about the Prescription Drug Repository Program and the P3 Program.		
		Prescription Drug Repository Program: Del. Rudolph reminded us of the meetings we had at the end of the last session concerning LTC facilities donating their left over partially used blister packs that have unopened unit doses remaining. He wants to have a conversation with Wendy Kronmiller, OHCQ, Lifespan and hfam, about encouraging the LTC community to donate the left over blister packs and perhaps becoming drop-off sites.		
		He said that he would contact Wendy Kronmiller to set up a meeting with OHCQ, Lifespan, hfam and the Board of Pharmacy.		
		He suggested we have two one page documents. One on disposal (we've written one of those) and one on the Rx Drug Rep Program with a flow chart of how it works.		
		He suggested we contact Ellen Yankellow to see if the prisons could donate or be a drop off site.		
		He anticipates that one of the concerns for the LTC facility is that they would not want to receive prescription medication drop-offs from the general public, but would want to limit donations to their residents. Is there any way that a drop-off site could limit the population they serve?		
		In a subsequent phone call with Linda Bethman she pointed out that the law/regs do not address this. If a facility does not service the general public, then they would not be obligated to accept donations from the general public.		
		We informed him of the September 25th National Take Back Day. He		

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		would like the Maryland Board of Pharmacy to be a co-sponsor of this event in MD, maybe even pull in the associations. He thinks having pharmacists there in their white coats would be great PR. He would like the concept to go before the Board on August 18th. Local Health Departments may also want to participate.		
		I reported on my conversation with Ernest Donovan, the MD DEA contact for the September event. Any location would have to have a sworn police officer present. There are no restrictions on the type of locations that participate.		
		3) P3 Program		
		Del. Rudolph would like to see a resolution from the Board in support of the P3 program.		
	B. M. Souranis, Chair, Licensing Committee	L. Naesea reported on the following Recommended Technician Training Programs: 1. Rite Aid Technician Program	B1. Motion: Licensing Committee made a motion to approve the technician program	B1. Board Action: The Board voted to approve the motion.
			H. Finke seconded the motion.	
		2. DTM Meeting was held on August 11, 2010. The Joint Committee made a recommendation to revise the DTM regulations and streamline the processes of the application.	B2. Motion: D. Chason made a motion to approve the recommendation of the DTM Committee.	B2. Board Action: The Board voted to approve the motion.
			H. Finke seconded the motion.	
IV. Other Business	A. M. Souranis	None		

Subject	Responsible		Action Due Date	Board Action
	Party	Discussion	(Assigned To)	
	B. Board	A. M. Handelman would like a task force to be developed to review	A. Motion:	A. Board Action:
	Member	regulations for Assisted Living Facilities.	M. Handelman	
	Updates		made a motion to	The Board voted
			develop a task	to approve the
			force for Assisted	motion.
			Living.	
			C. Anderson	
			seconded the	
			motion.	
V. Adjournment	M. Souranis,	The Public Meeting was adjourned at _12:09 P.M.	Motion:	Board Action:
	Board		D. Chason made a	The Board voted
	President	B. At 1:10 P.M. M. Souranis convened a Closed Public Session to	motion to close	to approve the
		conduct a medical review of technician applications.	the Public Meeting	motion.
			and open a	
		C. The Closed Public Session was adjourned at 1:32 P.M. Immediately	Closed Public	
		thereafter, M. Souranis convened an Administrative Session for	Meeting.	
		purposes of discussing confidential disciplinary cases. With the		
		exception of cases requiring recusals, the Board members present at the	D. Taylor	
		Public Meeting continued to participate in the Administrative Session.	seconded the	
			motion.	